

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2013-0007; NIOSH-233]

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014: Proposed Additions and Deletions to the NIOSH Hazardous Drug List

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Draft Document Available for Public Comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014: Proposed Additions and Deletions to the NIOSH Hazardous Drug List." The document and instructions for submitting comments can be found at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

This guidance document does not have the force and effect of law.

**PUBLIC COMMENT PERIOD:** Comments must be received by [Insert date, 60 days after publication date].

ADDRESSES: You may submit comments, identified by CDC-2013-0007 and Docket Number NIOSH-233, by either of the two following methods:

- Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a>
  Follow the instructions for submitting comments.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories,
   MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Instructions: All information received in response to this notice must include the agency name and the docket number (CDC-2003-0007; NIOSH-233). All relevant comments received will be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to CDC-2013-0007 and Docket Number NIOSH-233.

## SUPPLEMENTARY INFORMATION:

Background: The NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004

(<a href="http://www.cdc.gov/niosh/docs/2004-165/">http://www.cdc.gov/niosh/docs/2004-165/</a>). This Alert contained Appendix A which was a list of drugs that were deemed to be hazardous and may require special handling. This list of hazardous drugs was updated in 2010 and 2012 and covered all new approved drugs and drugs with new warning up to December 2009.

(http://www.cdc.gov/niosh/docs/2010-167/;

http://www.cdc.gov/niosh/docs/2012-150/). Between January 2010 and December 2011, 48 new drugs received FDA approval and 276 drugs received special warnings (usually black box warnings) based on reported adverse effects in patients. From this list of 324 drugs, 42 drugs were identified by NIOSH as candidate hazardous drugs. Four of these drugs had safe handling recommendations from the manufacturer and NIOSH is following the recommendations of the manufacturers. Therefore, these four drugs will be listed as hazardous without requiring further review. A panel consisting of peer reviewers and stakeholders was asked to review and comment on the remaining 38 potentially hazardous drugs. In addition, the panel members were asked to comment on the addition of one drug requested by several stakeholders and the removal of one drug from the 2012 Hazardous Drug List. Reviewers were not asked to provide a consensus

opinion and NIOSH made the final determination regarding additions and deletions to the 2014 hazardous drug List.

NIOSH reviewed the recommendations of the peer reviewers and stakeholders and determined that 24 drugs in addition to the 4 drugs with manufacturer's warnings, were determined to have one or more characteristics of a hazardous drug and this list of 28 drugs is being published for comment in CDC-2013-0007 and NIOSH Docket Number 233. In addition, 1 drug from the 2012 Hazardous Drug List is being considered for removal. The complete list of these drugs can be found at: <a href="http://www.regulations.gov">http://www.regulations.gov</a> as a supporting document.

FOR FURTHER INFORMATION CONTACT: Barbara MacKenzie, NIOSH, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C26, Cincinnati, Ohio 45226, telephone (513) 533-8132, E-mail hazardousdrugs@cdc.gov.

	May 24,	2013
John Howard	Date	

Director, National Institute for Occupational Safety and Health,
Centers for Disease Control and Prevention.

[FR Doc. 2013-13043 Filed 05/31/2013 at 8:45 am; Publication

Date: 06/03/2013]